

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/007651

International filing date (day/month/year)
10.03.2005

Priority date (day/month/year)
10.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61K31/01, A61K31/015, A61K31/07, A23L1/30, A61P39/06, A61P43/00

Applicant
TRUSTEES PG TUFTS COLLEGE TUFTS UNIVERSITY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Herrera, S

Telephone No. +49 89 2399-8464



BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/561413
IAP12 Rec'd PCT/PTO 19 DEC 2005
International application No.
PCT/US2005/007651

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/007651

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 8-20

because:

- ☒ the said international application, or the said claims Nos. 8-20 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form

- ☐ has not been furnished
- ☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

BEST AVAILABLE COPY

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/007651

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-20
Inventive step (IS)	Yes: Claims	1-20
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

3EST AVAILABLE COPY

Section III

Claims 8-20 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Section V

1. Reference is made to the following documents:
 - D1: WO 2005/027950 A (RAY AND TERRY'S HEALTH PRODUCTS, INC; GROSSMAN, TERRY; KURZWEIL, RAYMO) 31 March 2005 (2005-03-31)
 - D2: WO 01/17519 A (COGNIS DEUTSCHLAND GMBH; GAERTNER, CHRISTINE; STAHL, WILHELM; HEINRICH) 15 March 2001 (2001-03-15)
 - D3: EP-A-0 981 969 (BASF AKTIENGESELLSCHAFT) 1 March 2000 (2000-03-01)
 - D4: STAHL W ET AL: "Carotenoid mixtures protect multilamellar liposomes against oxidative damage: Synergistic effects of lycopene and lutein" FEBS LETTERS, ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL, vol. 427, no. 2, 8 May 1998 (1998-05-08), pages 305-308, XP002082207 ISSN: 0014-5793
 - D5: "LUTEIN LYCOPENE CAROTENE COMPLEX VEGICAPS"[Online] 3 March 1998 (1998-03-03), XP002125651 Retrieved from the Internet: URL:www.solgar.com/online_reference/beta_carotene/lutein.html>
 - D6: DE 101 09 798 A1 (AVENTIS PHARMA DEUTSCHLAND GMBH) 12 September 2002 (2002-09-12)
 - D7: WO 2004/108869 A (CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS; GARCIA MARTOS, JOSE M) 16 December 2004 (2004-12-16)
 - D8: DATABASE WPI Section Ch, Week 200260 Derwent Publications Ltd., London, GB; Class B07, AN 2002-560763 XP002230968 & JP 2002 128651 A (KOSE KK) 9 May 2002 (2002-05-09)
2. The subject-matter of the present claims is not novel in that compositions comprising lutein together with beta-carotene and/or lycopene in the amounts defined, having synergistic effect are known from the prior art (cf. D2-D6 and D8; parts indicated in

the search report). Also their uses as antioxidative agents, for reducing agents and in nutritional compositions are well known.

Consequently the requirements of Articles 33 (2) and (3) have therefore not been fulfilled.

3. For the assessment of the present claims 8-20 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Section VI

Certain documents cited

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO20050287950	31.10.2005	13.09.2004	12.09.2003
WO2004108869	16.12.2004	03.06.2004	06.06.2003

BEST AVAILABLE COPY